Original Article

Comparative Evaluation of Desensitizing Efficacy of Dentifrice Containing 5% Fluoro Calcium Phosphosilicate versus 5% Calcium Sodium Phosphosilicate: A Randomized Controlled Clinical Trial

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Abstract

Background: A considerable number of agents are effective in the treatment of dentin hypersensitivity (DH). The present 2 months' randomized clinical trial compared the desensitizing efficacy of dentifrice containing 5% fluoro calcium phosphosilicate versus 5% calcium sodium phosphosilicate in participants with sensitive teeth. **Materials and Methods:** A total of 60 participants above 18 years of age with a history of DH who displayed a visual analog scale (VAS) score of ≥ 4 to both subjective and thermal sensitivity in at least two teeth at the qualifying as well as baseline visit were considered eligible. Participants were randomly allocated to one of the following dentifrices: 5% fluoro calcium phosphosilicate; 5% calcium sodium phosphosilicate; and a standard dentifrice containing fluoride. Sensitivity scores (VAS) were measured at baseline, immediately after scaling and root planning, at 15, 30, and at 60 days. **Results:** A statistically significant reduction in symptoms for all treatment groups from baseline to 15, 30, and 60 days for both measures of sensitivity was observed. A significant reduction in DH with time for all the variables during the 8 weeks of the active phase of the study independent of treatment groups was noted. However, the fluoro calcium phosphosilicate group showed a higher degree of effectiveness in reducing DH, followed by calcium sodium phosphosilicate then standard fluoride dentifrices. **Conclusion:** Under the conditions of a clinical trial, the fluoro calcium phosphosilicate group showed a comparable reduction in the symptoms of DH.

Keywords: *Calcium sodium phosphosilicate, dentifrice, dentinal hypersensitivity, desensitizing toothpaste, fluoro calcium phosphosilicate, randomized clinical trial, visual analog score*

Introduction

Dentin hypersensitivity (DH) is a global epidemiological oral health problem affecting one or more teeth of many adult individuals. It is a common, transient oral pain condition, the pain resulting immediately on stimulation of exposed dentinal tubules and resolving on stimulus removal.[1] DH typically presents as a short, sharp pain which is of arresting nature, affecting quality of life.[2] It occurs in response to an external, thermal, chemical, tactile, or osmotic stimulus that cannot be ascribed to any other dental defect or disease.[3,4]

Data available from available studies concluded that the incidence of hypersensitivity ranges from 10% to 30% of the general population with higher female incidence than male, commonly affecting premolar and incisor teeth.[5] A recent study demonstrated 42% of 18–35-year-old individuals present with sensitivity.[6] The incidence of DH reportedly peaks during the third and fourth decades of life.[7]

Varied etiological and predisposing factors related to DH have been cited which include removal of enamel, as a result of wasting diseases, and gingival recession particularly associated with faulty tooth brushing and periodontal disease.[6,8] Pain elicited by DH can be rationalized by the widely acknowledged "hydrodynamic theory" proposed by Braennstroem and Astroem in 1964.[9] According to this theory, when exposed dentinal tubules come into contact with certain stimuli, the movement of dentinal fluid within the patent tubules stimulate the nerve terminals at the pulpal end of the tubule resulting in pain.

Currently, two treatment approaches are widely applied for DH, namely tubular

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occlusion and blockage of nerve activity. Tubular occlusion incorporates the use of a physical or chemical agent that occludes the dentinal tubules. These occluding agents include stannous, strontium or oxalate salts; arginine; silicas; and bioactive glasses.[10,11] Treatment strategies such as lasers and periodontal soft-tissue grafting also work on the same principle. In the second approach, depolarizing agents, such as potassium ions, are directly diffused to reduce intradental nerve activity.[12]

Professionally, applied products appear effective in the treatment of dentine hypersensitivity; however, there is insufficient evidence for the authors to recommend one agent compared to another.[6] Calcium sodium phosphosilicate, a particulate bioactive glass, has been incorporated into dental products to provide relief from DH.[13] Numerous investigations have shown that it physically occlude the dentinal tubules by binding preferentially to exposed tubules.[14,15] On exposure to the aqueous oral environment, calcium sodium phosphosilicate provides calcium and phosphate ions to form a hydroxycarbonate apatite-like layer on the dentine surface and within the tubules.[4,16] Recently, fluoro calcium phosphosilicate, a fluoride-containing bioglass is designed and optimized for desensitizing toothpaste.[17] This formulation differentiates from previous bioglass toothpastes by its higher phosphate content, the presence of CaF2 in the glass and the smaller average particle size.[17] It forms fluorapatite, rather than hydroxyapatite, on teeth which is much more resistant to acids produced by bacteria and promotes remineralization, particularly in combination with the calcium and phosphate released from the glass. The fluoro calcium phosphosilicate containing toothpaste was launched in 2016 in the UK (online only) and pharmacies in Germany and India.

Its efficacy in treating dentine hypersensitivity still needs to be demonstrated in clinical studies.

This study aimed to comparatively evaluate the desensitizing efficacy of dentifrice containing 5% fluoro calcium phosphosilicate versus 5% calcium sodium phosphosilicate in participants with sensitive teeth over a period of 2 months. Standard fluoride toothpaste with no known anti-sensitivity properties was also included as a control.

The study was conducted with the following objectives:

- To evaluate the desensitizing efficacy of dentifrice containing 5% fluoro calcium phosphosilicate in participants with sensitive teeth
- To evaluate the desensitizing efficacy of dentifrice containing 5% calcium sodium phosphosilicate in participants with sensitive teeth
- To compare the desensitizing efficacy of the two dentifrices.

Materials and Methods

The study was a single-center, interventional, double-masked, and randomized controlled clinical design. The study duration was 2 months (60 days), in which sensitivity scores were measured at baseline, immediately after scaling, and root planning, at 15, 30, and at 60 days. The research protocol was initially submitted to the Ethical Committee of Faculty of Dental Sciences, Ramaiah University of Applied Sciences, Bengaluru, India. After ethical approval, participants were selected from the outpatient section of the Department of Periodontics, Faculty of Dental Sciences, Ramaiah University of Applied Sciences, Bengaluru, India. The duration of the study was from March 2017 to June 2017.

The three dentifrices studied were as follows:

A. A commercially available dentifrice containing 5% fluoro calcium phosphosilicate
B. A commercially available dentifrice containing 5% calcium sodium phosphosilicate
C. A standard dentifrice containing fluoride.

Both the investigators and participants were masked to the contents of dentifrice. The dentifrices were provided by Group pharmaceutical Ltd, Bengaluru, in tubes labeled as A, B, and C, the contents of which were disclosed to the investigators only after completion of the statistical analyses.

The sample size was estimated using the software GPower v. 3.1.9.2 (GPower, Heinrich Heine University, Dusseldorf, Germany). Considering the effect size to be measured at 40%, power of the study at 80%, and the margin of the error at 15%, the total sample size calculated was 45. Seventy-three individuals were assessed for eligibility; of them, 60 individuals met inclusion criteria and were randomly assigned to one of three treatment groups using random allocation concealment. Participants who could fulfill the scheduled appointment, and gave written informed consent to participate were recruited into trial. A consort chart of the study is shown in Figure 1.

Inclusion and exclusion criteria

Participants above 18 years of age with a history of DH were selected at baseline. Participants who displayed a visual analog scale (VAS) score of ≥4 to both subjective and

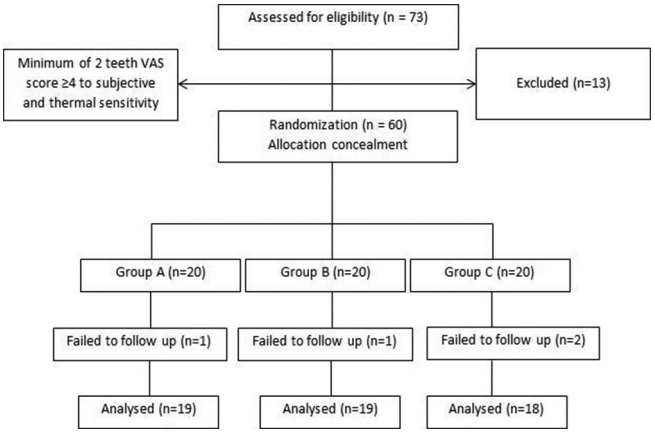


Figure 1: Consort chart

thermal sensitivity in at least two teeth at the qualifying as well as baseline visit were considered eligible for the study.

Participants with active cervical caries or attrited teeth with caries or chipped teeth and participants reporting with regular use of a desensitizing dentifrice within 2 months before the start of the study were excluded. Besides, participants who have undergone periodontal surgery in the preceding 6 months, or dental prophylaxis within 2 weeks of the projected start of the study, patients on daily doses of certain medications, including analgesics, anticonvulsants, antihistamines, sedatives, tranquilizers, mood-altering drugs or anti-inflammatory drugs, pregnant and lactating females were excluded from the study. Participants were also excluded if they were allergic to ingredients used in the study.

Sensitivity assessment

The enrolled participants were evaluated for following measures/tests of sensitivity:

- Subjective sensitivity: Individuals were asked to evaluate their typical perceived pain level due to dentine hypersensitivity using VAS
- Thermal sensitivity: Scoring of sensitivity was done by one-second application of cold air from a standard dental air syringe at 40–65 psi at ambient temperature, directed perpendicular and at a distance of 1–3 mm from the exposed dentin surface. The adjacent teeth were isolated with cotton rolls and protected by gloved fingers before applying the stimuli to prevent false-positive results. The intensity of pain evoked was marked by the subject on a 10 cm VAS.

Sensitivity was measured using a 10 cm VAS score, with the score of 0 being a no-pain response and a score of 10 being extreme pain or discomfort.[18,19]

Subjective and thermal sensitivity scores were recorded at baseline followed by scaling and root planning. The clinical examinations and sensitivity tests were carried out by a single examiner. Each participant was given respective dentifrice along with a soft-bristled toothbrush and was instructed to brush their teeth immediately after scaling and root planing (SRP) for 2 min. All the participants were instructed to apply dentifrice in an amount equal to about half the length of the bristle head and were also instructed to brush for 2 min and no more than a total of 2 times/day. Participants were also directed to refrain from any other dentifrice or mouth rinse during the study. VAS was recorded immediately after SRP followed by tooth brushing. This was intended to provide a claim for immediate relief. Participants were recalled at 15 days, 30 days, and at 60 days to record the VAS scores for both subjective and thermal sensitivity.

Statistical analyses

Statistical analyses were performed using Statistical Package for Social Sciences (SPSS) for Windows, Version 22.0 released 2013. IBM Corp, Armonk, NY, USA. Descriptive analysis of all study parameters was done mean and standard deviation for quantitative variables, frequency, and proportions for categorical variables. One-way ANOVA test followed by Bonferroni's *post hoc* analysis was used to compare the mean VAS scores by subjective and thermal sensitivity between the three groups at different time intervals. Repeated measures of ANOVA followed by Bonferroni's *post hoc* analysis were used to compare the mean VAS scores of subjective and thermal sensitivity between different time intervals within each study group. The level of statistical significance was set at $P < 0.05$.

Results

Table 1 presents demographic data of the study population. The mean age of participants enrolled in group A was 38.4 years (8 males and 12 females), 44 years in group B (10 males and 9 females), and 42.1 years in group C (11 males and 8 females).

Mean VAS scores for subjective sensitivity and thermal sensitivity for the fluoro calcium phosphosilicate group, the calcium sodium phosphosilicate group, and the fluoride group at baseline, immediately after SRP, 15, 30, and 60 days are shown in Tables 2 and 3, respectively. No statistically significant difference was observed between the subjective and thermal sensitivity VAS scores in all the three groups at baseline and immediately after treatment. At 15, 30, and 60 days statistically significant reductions in VAS scores were observed in the three groups.

Intragroup comparison of mean VAS scores for subjective sensitivity and thermal sensitivity between different intervals is shown in Graphs 1 and 2, respectively. Statistically significant reductions in the scores were observed from baseline to 60 days in the three groups.

Intergroup comparison for subjective sensitivity and thermal sensitivity revealed that the fluoro calcium phosphosilicate group was significantly better in reducing VAS scores than the calcium sodium phosphosilicate group and fluoride group at 15, 30, and 60 days. Furthermore, calcium sodium phosphosilicate group showed statistically significant reduction in the scores when compared to the fluoride group [Tables 4 and 5].

Table 1: Distribution of demographic characteristics among study participants

Variables	Group A	Group B	Group C
Age, mean (SD)	38.4 (9.0)	44.0 (12.3)	42.1 (9.9)
Range	23-53	22-59	23-57
Sex, *n* (%)			
Males	8 (40.0)	10 (52.6)	11 (57.9)
Females	12 (60.0)	9 (47.4)	8 (42.1)

SD: Standard deviation

Table 2: Comparison of mean visual analog scale scores for subjective sensitivity between three study groups using one-way ANOVA followed by Bonferroni's *post hoc* analysis

Time	Groups	Mean	SD	SE	Minimum	Maximum	*F*	*P*
Baseline	Group A	7.77	0.95	0.21	5.9	8.9	0.411	0.67
	Group B	7.64	0.84	0.19	5.8	9.2		
	Group C	7.52	0.82	0.19	5.6	8.7		
After Rx	Group A	7.17	0.89	0.20	5	8.6	0.228	0.80
	Group B	7.19	0.80	0.18	5.5	8.5		
	Group C	7.34	0.83	0.19	5	8.5		
At 15 days	Group A	4.91	0.22	0.05	4.5	5.3	235.627	<0.001*
	Group B	5.60	0.22	0.05	5.2	5.9		
	Group C	6.43	0.22	0.05	5.9	6.7		
At 30 days	Group A	3.49	0.23	0.05	3	3.8	630.427	<0.001*
	Group B	4.46	0.21	0.05	4.1	4.8		
	Group C	6.13	0.25	0.06	5.5	6.4		
At 60 days	Group A	2.43	0.22	0.05	1.9	2.8	578.873	<0.001*
	Group B	3.62	0.21	0.05	3.3	3.9		
	Group C	5.28	0.34	0.08	4.7	5.9		

*Statistically significant; SD: Standard deviation; SE: Standard error

Table 3: Comparison of mean visual analog scale scores for thermal sensitivity between three study groups using one-way ANOVA followed by Bonferroni's *post hoc* analysis

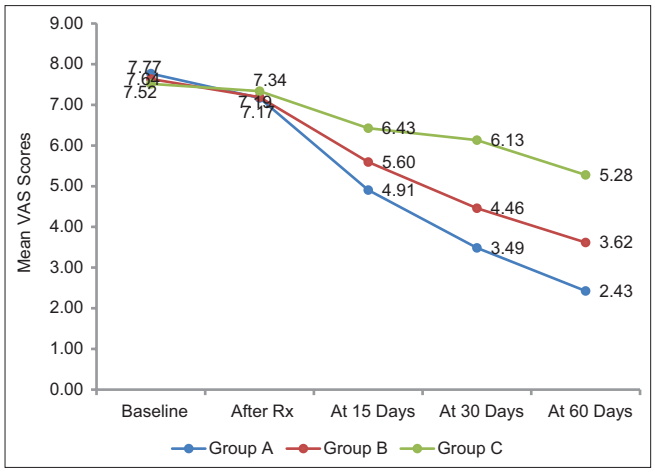
Time	Groups	Mean	SD	SE	Minimum	Maximum	*F*	*P*
Baseline	Group A	7.86	0.89	0.20	6.3	9.2	1.145	0.33
	Group B	7.56	0.83	0.19	6.2	8.9		
	Group C	7.47	0.79	0.18	6.3	8.7		
After Rx	Group A	7.32	0.77	0.17	5.8	8.5	1.520	0.23
	Group B	7.08	0.78	0.18	5.9	8.4		
	Group C	7.52	0.74	0.17	6.4	8.9		
At 15 days	Group A	4.86	0.25	0.06	4.4	5.4	214.156	<0.001*
	Group B	5.67	0.20	0.05	5.3	5.9		
	Group C	6.36	0.22	0.05	5.9	6.8		
At 30 days	Group A	3.54	0.22	0.05	3	3.9	621.450	<0.001*
	Group B	4.41	0.18	0.04	4	4.7		
	Group C	6.07	0.27	0.06	5.4	6.5		
At 60 days	Group A	2.54	0.16	0.04	2.2	2.8	462.751	<0.001*
	Group B	3.51	0.21	0.05	3.1	3.8		
	Group C	5.26	0.42	0.10	4.4	5.7		

*Statistically significant; SD: Standard deviation; SE: Standard error

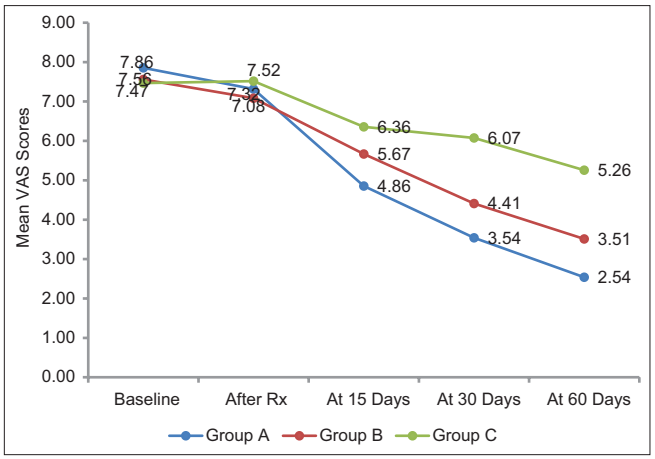
Discussion

This study compared fluoro calcium phosphosilicate dentifrice to calcium sodium phosphosilicate and standard fluoride dentifrices. The sensitivity level of this study was determined by translating the subjective feedback scale into objective data using VAS scale. The validity and reliability of the VAS for measuring both experimental and clinical pain have been demonstrated by several investigators.[8,10,14] The results of the present study revealed statistically significant reduction in symptoms for all treatment groups from baseline to 15, 30, and 60 days for both measures of sensitivity. A significant reduction in DH with time for all the variables during the 8 weeks of the active phase of the study independent of treatment groups was noted. However, the fluoro calcium phosphosilicate group showed a higher degree of effectiveness in reducing DH, followed by calcium sodium phosphosilicate then standard fluoride dentifrices.

Fluoro calcium phosphosilicate is a fluoride-releasing bioactive glass recently incorporated in desensitizing dentifrices. It differs from the conventional calcium sodium phosphosilicate by the presence of CaF_2 in the glass, higher phosphate content and smaller average particle size (D_{50} of 6 μm).[17] Studies have reported that fluoride ions are released by fluoride-containing bioactive glasses during dissolution[20] resulting in the formation of fluorapatite.[21] Moreover, the presence of CaF_2 increases glass dissolution and higher phosphate content enhances the ability to form apatite crystal.[17,22] Fluoro calcium phosphosilicate dentifrices have shown to instantly occlude



Graph 1: Comparison of mean Visual Analog Scale scores for subjective sensitivity between different time intervals within each study group



Graph 2: Comparison of mean visual analog scale scores for thermal sensitivity between different time intervals within each study group

Table 4: Bonferroni's *post hoc* analysis for comparing mean visual analog scale scores between groups for subjective sensitivity

Time	Group	Group A versus Group B	Group A versus Group C	Group B versus Group C
At 15 days	*P*	<0.001*	<0.001*	<0.001*
At 30 days	*P*	<0.001*	<0.001*	<0.001*
At 60 days	*P*	<0.001*	<0.001*	<0.001*

*Statistically significant

Table 5: Bonferroni's *post hoc* analysis for comparing mean visual analog scale scores between groups for thermal sensitivity

Time	Group	Group A versus Group B	Group A versus Group C	Group B versus Group C
At 15 days	*P*	<0.001*	<0.001*	<0.001*
AT 30 days	*P*	<0.001*	<0.001*	<0.001*
At 60 days	*P*	<0.001*	<0.001*	<0.001*

*Statistically significant

some of the dentinal tubules, after 2 min of brushing. Even after washing with 6% citric acid for 30 s, the tubules were reported to remain occluded.[17] This may explain the instant relief experienced by some patients in this study after they were asked to brush immediately after SRP although the results were statistically insignificant.

The significant clinical improvement of hypersensitivity through the formation of fluorapatite in the present study may aid to hypothesize that fluoro calcium phosphosilicate could be useful in remineralization and the prevention of demineralization of tooth structures, especially dentin. Besides, it also inhibits the metabolism of bacteria associated with caries, by preventing their metabolic acid production.[17]

In the present study, 5% calcium sodium phosphosilicate dentifrice was used as a positive control.

Calcium sodium phosphosilicate, initially developed as a bone regenerative material, forms hydroxyapatite-like mineral layer, and effectively occludes dentinal tubules.[14,15,23] *In vitro* and clinical *in situ* studies confirm that calcium sodium phosphosilicate occludes patent dentinal tubules.[24,25] Evidence from clinical studies support that dentifrices containing 5%–7.5% calcium sodium phosphosilicate effectively relieves DH.[8,14,26-31] In the present study, the calcium sodium phosphosilicate group showed significant percentage reduction in both the subjective and thermal sensitivity measures but reduction compared to the fluoro calcium phosphosilicate group was less although the reduction was statistically higher than the standard fluoride group. The difference in sensitivity reduction between the two bioglass containing dentifrices can be explained by their mechanism of action.

The standard fluoride dentifrices employed in the present study also reported greater reduction in mean sensitivity scores over time. The unexpected improvement in sensitivity in the third group may be explained by the Hawthorne effect described as a change in subject behaviour as a result of participating in an observed study.[32] This would probably influence the brushing habits of the patients during the study leading to improved oral hygiene, in turn providing greater salivary access to the patent dentinal tubules; enhancing the deposition of salivary proteins, calcium and phosphate, and occluding the tubules. Furthermore, West *et al*.[33] reported, the relief obtained by the patients without any treatment may be attributed to the placebo effect, varying from 20% to 60% in DH clinical trials. Placebo effect is described as a response that results from the action of intervention rather than any particular mechanism of action.[33]

Clinical studies demonstrating the efficacy of fluoro calcium phosphosilicate as a desensitizing agent are limited. The data from this trial provide evidence of the therapeutic value of fluoro calcium phosphosilicate dentifrices, suggestive that it can be used in the reduction

of and symptoms/pain due to dentine hypersensitivity in-comparable to other conventional desensitizing agents.

Conclusion

All the three treatment groups showed a reduction in VAS score for both subjective and thermal sensitivity, after 60 days of clinical evaluation, compared with baseline, irrespective of their different modes of action. Five percent fluoro calcium phosphosilicate group showed statistically significant reduction in VAS scores when compared to calcium sodium phosphosilicate and fluoride containing dentifrices. In addition, clinically significant reduction in sensitivity response was observed in the fluoro calcium phosphosilicate group immediately after SRP suggestive of providing immediate relief. Therefore, fluoro calcium phosphosilicate dentifrices may provide a new direction for the treatment of dentinal hypersensitivity.

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Conflicts of interest

There are no conflicts of interest.

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